

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

**IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION**

MDL No. 2326

**THIS DOCUMENT RELATES TO ALL BOSTON SCIENTIFIC WAVE 4 CASES IN
EXHIBIT A**

**BOSTON SCIENTIFIC’S MOTION TO EXCLUDE THE GENERAL CAUSATION
TESTIMONY OF DR. BRUCE ROSENZWEIG, M.D AND MEMORANDUM IN
SUPPORT**

Defendant Boston Scientific Corporation (“Boston Scientific”), pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), hereby submits this Motion to Exclude the Testimony of Dr. Bruce Rosenzweig and Memorandum in Support. Boston Scientific asks the Court to adopt its prior rulings relating to Dr. Rosenzweig’s general causation opinions set forth in its May 29, 2018, order. ECF No. 6039. The following brief seeks to exclude the general causation opinions of Dr. Rosenzweig that the Court has previously excluded.

Introduction

Dr. Bruce Rosenzweig is a urogynecologist who practices in Illinois, whom Plaintiffs have designated to offer general and specific causation opinions. Dr. Rosenzweig’s general causation opinions were previously set forth in his Wave 1 and Wave 2 Expert Report for cases involving the Advantage, Advantage Fit, and Lynx devices. *See* Expert Report For Cases Involving an Advantage, Advantage Fit, and Lynx.¹ Dr. Rosenzweig filed an updated report now applying to

¹ Expert Report of Dr. Bruce Rosenzweig Relating to All Boston Scientific Wave I and II Cases Involving An Advantage Sling, An Advantage Fit Sling, or a Lynx Sling, attached as **Exhibit A**.

the following Boston Scientific products: Advantage, Advantage Fit, Lynx, Solyx, Prefyx, Uphold, and Pinnacle.² As it did with respect to the Wave I, II, and III cases, this Court should exclude certain of Dr. Rosenzweig's general opinions because they are unreliable, he lacks the qualifications to offer them, and they will not be helpful to a jury. *See Griffin v. Boston Scientific*, No. 2:13-cv-11876, 2016 WL 3031700 at *10-12 (S.D. W.Va. 2016) (excluding certain general causation opinions of Dr. Rosenzweig); ECF No. 6039 (same).

First, Dr. Rosenzweig's offers many improper opinions that constitute nothing more than a narration of Boston Scientific documents suggesting the company's state of mind or corporate conduct. Second, he is not qualified to opine on the testing of mesh products. Third, any attempt to offer opinions regarding the association between mesh and cancer should be excluded because they are not helpful to a jury but are extremely prejudicial. Fourth, he offers some opinions that constitute improper legal conclusions. Finally, his opinion that these products should not be used in the body because of the manufacturer's medical application caution is not helpful to the jury. In *Griffin*, this Court held that these opinions should be excluded. *Id.* at *2, *10-12. In Wave IV cases, Dr. Rosenzweig does not offer any additional basis supporting these opinions, but rather relies on the a very similar general report adopting his general opinions to all Boston Scientific mesh products with the same basis proffered in the Wave I, II, and III cases. As discussed more fully below, these opinions remain deficient and should be excluded.

Legal Standard

The Federal Rules of Evidence and the Supreme Court's decisions in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), require the trial judge, as a gatekeeper, to determine whether an expert's testimony is

² Expert Report of Dr. Bruce Rosenzweig in Wave 4, attached as **Exhibit B**.

reliable and relevant. FED. R. EVID. 702; *Daubert*, 509 U.S. at 598; *Kumho Tire Co.*, 526 U.S. at 141.³ The proponent of the expert opinion bears the burden of establishing its admissibility. *See, e.g., Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Under Federal Rule of Evidence 702, an expert opinion must satisfy three prerequisites before being admitted. First, the expert must be adequately qualified by virtue of “knowledge, skill, experience, training or education,” which is sufficiently related to the particular subjects at issue in the case. FED. R. EVID. 702; *see, e.g., Cooper v. Lab. Corp. of Am. Holdings, Inc.*, 150 F.3d 376, 380 (4th Cir. 1998). The offered expert opinion must not go “beyond the expert[']s qualifications.” *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011).

Second, the expert’s opinion must assist “the trier of fact to understand the evidence or to determine a fact in issue.” FED. R. EVID. 702(a). Admissibility under this prerequisite requires “an analysis of whether the opinion is relevant to the facts at issue.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999). If the opinion “does not relate to any issue in the case,” it is inescapably “not relevant and ergo not helpful.” *Daubert*, 509 U.S. at 591. The question is “one of ‘fit,’” a quality that “is not always obvious.” *Id.* This requirement is, however, demanding. “[S]cientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Id.*

Further, the expert testimony must not be a mere regurgitation of factual information. *Hines*, No. 2:04-0690, 2011 WL 2680842, at *5. Expert testimony that “states a

³ Federal law governs the admissibility of expert testimony in diversity actions. *See, e.g., Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005). In multidistrict litigation, the law of the transferee circuit governs on federal law. *See, e.g., In re Temporomandibular Joint Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) (“In the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law.”).

legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.” *U.S. v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). The expert must offer knowledge beyond the understanding of the average juror; testimony that will not assist the jury must be excluded. *Persinger v. Norfolk & W. Ry. Co.*, 920 F.2d 1185, 1188 (4th Cir. 1990) (affirming district court’s exclusion of expert opinion because it “did no more than state the obvious.”).

Third, the expert’s opinion and methodology must be reliable and the expert must reliably apply the methodology to the facts of the case. *Daubert*, 509 U.S. at 592-93. “A bold statement of the experts’ qualifications, conclusions, and assurances of reliability are not enough to satisfy the *Daubert* standard.” *Doe 2 v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 471 (M.D.N.C. 2006). To be deemed reliable, the expert’s opinion “must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.” *Oglesby v. Gen. Motors Corp.*, 190 F. 3d 244, 250 (4th Cir. 1999) (emphasis in original). Most importantly, the expert testimony must be trustworthy. *Westberry*, 178 F.3d at 260. Expert witnesses must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co.*, 526 U.S. at 152.

In determining the reliability of an expert opinion, *Daubert* provides the following factors for consideration: “(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.” *Smith & Nephew, Inc.*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592–94). These factors are “neither

definitive, nor exhaustive.” *Id.* at 199-200. In light of the variability of the analysis, “the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.” *Kumho Tire Co.*, 526 U.S. at 152.

Expert testimony can be “both powerful and quite misleading.” *Daubert*, 509 U.S. at 595. Where the proponent fails to establish all of the prerequisites, the exclusion of expert testimony is within the court’s sound discretion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997).

ARGUMENT

A. State of Mind And Corporate Conduct Opinions Will Not Assist The Jury.

Much of Dr. Rosenzweig’s general report comprises a narration of Boston Scientific documents suggesting the company’s state of mind or corporate conduct rather than proper expert opinion. As this Court has repeatedly held in this MDL, experts may not “usurp the jury’s fact finding function by allowing an expert to testify as to a party’s state of mind or on whether a party acted reasonably.” *See, e.g.*, Wave 3 Order (ECF No. 6039); *Griffin*, 2016 WL 3031700 at *2; *Tyree v. Boston Scientific*, 2:12-cv-08633, 2014 WL 548669, *6 -7 (S.D. W. Va. Oct. 17, 2014); *Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, *3 (S.D. W. Va. July 8, 2014); *Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013). This Court has also noted that “[a]lthough an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party’s knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these

matters will not assist the jury.” *See Tyree*, 2014 WL 5486694 at *6 -7. Once again, the Court should prohibit Dr. Rosenzweig from offering such opinions.

Dr. Rosenzweig spends a significant portion of his general report regurgitating Boston Scientific’s internal documents, which were provided to him by Plaintiffs’ counsel. *See* General Report; Dep. I at 63:17-21.⁴ Using these documents, he regurgitates, for example:

- Boston Scientific’s literature searches regarding mesh complications.
- Presentations seen and given by Boston Scientific employees regarding mesh complications as well as the company’s presentations at national sales meetings.
- Internal BSC emails regarding potential sponsorship of clinical studies.
- Internal emails regarding “concerns raised” about the Boston Scientific’s 1990s polyester sling, the Protegen.
- Internal Boston Scientific emails, allegedly to show claims made “to the public...that are not supported by relevant and reliable data,” but which in fact were never presented to the public.

He also repeatedly opines on Boston Scientific’s state of mind. *See, e.g.*, Wave 4 Report at Opinion A.7; Opinion C.

None of these recitations of corporate documents or speculation regarding Boston Scientific’s state of mind are used to explain the basis of his opinions, but instead are used to paint a plaintiff-friendly portrait of Boston Scientific’s corporate conduct and state of mind. Such opinions should be excluded.

B. Dr. Rosenzweig Is Not Qualified to Offer Opinions on Product Testing.

⁴ Relevant portions of the General MDL Wave I and II Deposition of Dr. Rosenzweig (Nov. 25, 2014) (“Dep. I”) are attached as **Exhibit C**.

Dr. Rosenzweig has no specialized training or education that qualifies him to offer opinions on the testing of mesh products. His only experience in product development involved the creation of an amnioinfusion catheter (used to infuse fluid into the uterus during labor) in the late 1980s. Dep. I at 241:9-242:10. He did not conduct any pre-market testing on the product. *Id.* at 241:9-242:10; 292:6-14. He has no experience designing implantable medical devices like vaginal mesh, nor does he have experience personally drafting product labeling for such products. He is unqualified to offer opinions regarding the design and adequacy of warnings for the Advantage, Advantage Fit, and Lynx, including:

- Boston Scientific should have conducted testing to determine if mesh would degrade in the body. Report at 18-19.
- Boston Scientific did not undertake long term testing to determine if warnings in the MSDS were associated with long term consequences of use of mesh. *Id.* at 22-26.
- Boston Scientific “should have” conducted clinical trials prior to marketing its products. *Id.* at 34.

This Court has previously excluded Dr. Rozenzweig’s testimony on product testing. *Griffin*, 2016 WL 3031700 at *11. The Court explained:

While Dr. Rosenzweig has years of experience operating with polypropylene mesh products, his expert report does not convey any similar experience, education, or knowledge about the appropriate testing a medical device manufacturer should perform on its products prior to sale. Therefore, I agree with BSC and find Dr. Rosenzweig unqualified to testify on the adequacy or inadequacy of BSC's product testing.

Id. The Court had the same ruling Wave III. *See* ECF No. 6039. The Court should reach the same result here.

C. Cancer Opinions Must be Excluded.

Dr. Rosenzweig has offered an opinion that there is an association between cancer and polypropylene mesh which he believes “is going to be elucidated much more in the future.” Dep. I at 146:3-148:23. He acknowledges that no *causal* link has been established but noted that, if asked, he is prepared to testify as to the association between polypropylene and sarcomas. *Id.*

This Court has consistently excluded from evidence irrelevant and prejudicial opinions regarding any potential link between cancer and polypropylene mesh. In *Tyree*, the Court excluded a plaintiff’s expert’s testimony on the carcinogenicity of polypropylene on the grounds that none of the plaintiffs in that case claimed that the device caused cancer and “the mention of cancer in the context of this case...would, at a minimum, offend Rule 702 and confuse the jury on a matter with scant probative value.” *Tyree*, 2014 WL 5486694 at 63. Here, as in *Tyree*, such opinions are clearly irrelevant and have no probative value.

Such opinions should also be excluded because Dr. Rosenzweig failed to disclose them in his Rule 26 Report. Expert Reports under Fed. R. Civ. P. 26(a)(2)(B) must include “a complete statement of all opinions the witness will express and the basis and reasons for them.” There is no mention of “cancer,” “carcinogenicity,” or “sarcoma,” anywhere in his report. In determining whether nondisclosure of evidence is “substantially justified or harmless” under Fed. R. Civ. P. 37, a district court may consider 1) the surprised to the party against whom the witness was to have testified, 2) the ability of the party to cure that surprise, 3) the extent to which allowing the testimony would disrupt trial, 4) the explanation for the party’s failure, and 5) the importance of the testimony. *Hoyle v. Freightliner, LLC*, 650 F.3d 321, 329 (4th Cir. 2011). These factors weigh against admission: the opinions would disrupt trial without offering any probative evidence and he has offered no explanation for his failure to disclose them in his report. For these reasons, Dr. Rosenzweig’s opinions on carcinogenicity should be excluded. *See Griffin*, 2016 WL 3031700 at

*11 (excluding Dr. Rosenzweig's opinions on carcinogenicity); Wave III Order [ECF No. 6039] (same).

D. Dr. Rosenzweig Lacks the Necessary Experience and Knowledge to Give His Opinions Regarding the MSDS.

Dr. Rosenzweig also offers the opinion that the Boston Scientific mesh products should not be used in the body because the manufacturer of the raw polypropylene has included in its MSDS a medical application caution stating that the material should not be permanently implanted in the human body. *See* Report at 22-26. He also opines that Boston Scientific should have given the MSDS to doctors. Such opinions should be excluded because they are beyond his experience and knowledge.

As this Court explained in *Griffin* and adopted in Wave III:

Dr. Rosenzweig's opinion about the MSDS enters subject matters about which he is not qualified to testify. Specifically, Dr. Rosenzweig concludes that BSC did not perform the necessary testing that it should have to investigate the MSDS warning. As explained above, Dr. Rosenzweig lacks the experience and knowledge necessary to opine on what testing a manufacturer should perform on his products.

See Griffin, 2016 WL 3031700 at *12. As in *Griffin*, Dr. Rosenzweig's general opinions about the MSDS should be excluded in their entirety.

CONCLUSION

For the foregoing reasons, Boston Scientific respectfully requests this Court grant its Motion to Exclude the Testimony of Dr. Bruce Rosenzweig, M.D.

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Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2018, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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